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EXAMINER	
HISSONG, BRUCE D	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,027	DEL CURTO, MARIA DORLY	
	Examiner	Art Unit	
	Bruce D. Hissong, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 32-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 32-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *6/8/2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/9/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

1. The present application was received on 6/8/2006 and has been entered into the record.

2. Claims 1-25 and 32-37 are pending and are the subject of this office action.

Information Disclosure Statement

The information disclosure statement received on 2/9/2007 has been fully considered.

Drawings

The drawings received on 6/8/2006 are objected to for the following reasons: The text, including axis labels, of figures 1-5 and 10-12 is very small and difficult to read.

Specification

The specification is objected to for containing an embedded hyperlink (p. 6, line 5). Applicants are reminded that embedded hyperlinks and/or other forms of browser-executable code are not permitted (MPEP § 608.01).

Claim Objections

1. The Examiner suggests amending either claim 1 to recite "2-methylpropyl-beta-cycldextrin (HPBCD)", or claims 24 and 32(x) to fully define the acronym "HPBCD".

2. The Examiner suggests amending claims 12-14 to read "said antioxidant" rather than "said the antioxidant".

3. Claim 33 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim is drawn to the article of manufacture of claim 32, wherein said container is for "mono-dose" administration or "multi-dose" administration. A given article of manufacture that is a container for administration would necessarily be for either mono- or multi-dose (i.e one or more than one) administration because these would be the only possibilities, and therefore claim 33 does not further limit claim 32.

Claim Rejections - 35 USC § 112, first paragraph – written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-25 and 32-37 are rejected under 35 U.S.C. 112, first paragraph, containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to stabilized liquid pharmaceutical compositions, or an article of manufacture, comprising an IFN, or an isoform, mutein, fused protein, functional derivative, active fraction or salt thereof. The specification describes known IFN polypeptides, such as IFN-α, -β, and -γ, and also describes well-known IFN mutants such as Rebif™, Avonex™, and Betaferon™. The specification, on pages 5-10, describes “muteins" of IFN as "analogs of IFN in which one or more of the amino acid residues of a natural IFN are replaced by a different amino acid residue, or are deleted, or one or more amino acids residues are added to the natural sequence of IFN" without considerably changing the activity of the resulting protein. Similarly, "functional derivatives" are described as derivatives of IFN in which may be prepared from functional groups which occur as side chains on the residues of the N- or C-terminal groups, as long as they remain pharmaceutically acceptable and do not confer toxic properties on compositions comprising said functional derivatives. "Active fractions" of IFN, or muteins

and fused proteins, are described any fragment or precursor of the polypeptide chain of the protein molecule alone or together with the associated molecules or residues linked thereto.

However, as thus described, the claimed muteins, functional derivatives, or active fragments can encompass all possible IFN polypeptides in which any number of amino acid additions, deletions, or substitutions have occurred, or any fragment of an IFN molecule which has some level of any "activity". The specification does not describe which residues or regions of various IFN polypeptides can be modified in such ways, or describe any fragment(s) of any IFN polypeptide that could be considered an "active fraction". Furthermore, the claims do not require the muteins, functional derivatives, or active fractions of the instant invention to have any biological activity other than to retain some level of activity compared to the corresponding IFN, nor any particular structure. Thus, the specification has not described the claimed genus of IFN muteins, functional derivatives, and active fragments in such a way as to convey to a person of ordinary skill in the art that the Applicants had possession of the claimed genus at the time of invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a requirement that the claimed stabilized pharmaceutical composition or article of manufacture comprise any IFN mutein, functional derivative, or active fragment thereof. There is no identification of any particular portion of any IFN that must be conserved in order to maintain function. Accordingly, in the absence of sufficient distinguishing characteristics, the specification does not provide adequate written description of the claimed genus.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-22 recites the limitation of a "said bacteriostatic agent" in claim 18. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-11, 13-19, 21-22, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shirley *et al* ("Shirley" - US 2002/0172661) in view of Dorin *et al* ("Dorin" - US 5,814,485).

The claims of the present invention are drawn to stabilized pharmaceutical compositions comprising an IFN, isoform, mutein, fused protein, functional derivative, or active fraction thereof, and further comprising a buffer, 2-hydroxypropyl-beta-cyclodextrin, an isotonicity agent, and an anti-oxidant. The claims are further drawn to compositions comprising IFN-β at various concentrations, including recombinant IFN-β, and buffers, and specifically acetate buffer, at various concentrations and in an amount sufficient to maintain the pH of the composition within plus or minus 0.5 units of a specified pH, wherein the specified pH is about 3 to about 6. The claims also specifically recite mannitol as the isotonicity agent at various concentrations.

Shirley teaches stabilized liquid (i.e. aqueous) formulations of IFN-β (paragraphs 0002, 0039), including recombinant IFN-β (see claim 32) in a solution with a buffer, wherein the buffer is in an amount sufficient to maintain the pH of the composition within plus or minus 0.5 units of a specified pH, wherein the specified pH is about 3.0 to about 5.0 (see claim 1), and wherein the IFN-β concentration can range from 0.01 mg/ml to 20 mg/ml (10 μg/ml - 20,000 μg/ml - paragraph 0069) Shirley teaches numerous suitable buffers, including acetate buffer at a concentration range of 1 - 30 mM (paragraph 0034). Shirley also teaches that this composition can further comprise a "tonicifying agent" such as mannitol (paragraph 0038). Also disclosed is the inclusion of EDTA (paragraph 0072), disclosed as an agent that "acts as a scavenger of metal ions known to catalyze many oxidation reactions" and which the present specification lists as a suitable anti-oxidant. Shirley also teaches inclusion of bacteriostatic agents (paragraph 0048). Therefore, Shirley teaches a liquid composition comprising recombinant IFN-β which may comprise a buffer (acetate buffer), an isotonicity agent (mannitol), and an anti-oxidant (EDTA), as well as bacteriostatic agents. Shirley is silent regarding a stabilized composition comprising 2-hydroxypropyl-beta-cyclodextrin.

However, Dorin teaches compositions comprising IFN-β, and teaches that these IFN-β formulations can comprise 2-hydroxypropyl-beta-cyclodextrin, and also teaches that inclusion of 2-hydroxypropyl-beta-cyclodextrin is useful as a protectant because helps reduce the physical and chemical alterations to IFN-β polypeptides, such as oxidation. Dorin also teaches that 2-hydroxypropyl-beta-cyclodextrin helps prevent unwanted aggregation, chemical linkage, oxidation, and degradation of IFN-β (column 13, lines 6-31, and especially lines 21-31).

Therefore, a person of ordinary skills in the art, at the time the present invention was conceived, would have been motivated to create a stabilized liquid pharmaceutical composition comprising IFN-β, including recombinant IFN-β, and further comprising a buffer, 2-hydroxypropyl-beta-cyclodextrin, an isotonicity agent, and an anti-oxidant by following the combined teachings of Shirley and Dorin. The motivation to do so comes from Shirley, which teaches that compositions of recombinant IFN-β can be stabilized by formulation in mannitol, acetate buffer, and an anti-oxidant (EDTA), and also teaches that the buffer should be present in an amount sufficient to maintain the pH of the composition within plus or minus 0.5 units of a specified pH, wherein the pH is about 3 to about 5. Furthermore motivation is provided by Dorin, which teaches that 2-hydroxypropyl-beta-cyclodextrin is a useful as a protectant in IFN-β formulations. Therefore, because Shirley and Dorin both teach stabilized IFN-β formulations, and furthermore teach formulation with acetate buffer, mannitol, an anti-oxidant, and 2-hydroxypropyl-beta-cyclodexrin, and further comprising a bacteriostatic agent, a person of ordinary skill in the art would be motivated to create a composition comprising IFN, including recombinant IFN-β, and further comprising an acetate buffer, mannitol as a "tonicifying" agent (which can interpreted as an isotonicity agent), 2-hydroxypropyl-beta-cyclodextrin, and an anti-oxidant.

It is also noted that Shirley teaches a pH ranges which encompasses the pH of claim 5, acetate concentrations meeting the limitations of claim 6, and IFN-β concentrations meeting the limitations of claims 15 and 17. Regarding claims reciting concentrations or amounts that are not specifically disclosed in either Shirley or Dorin, however, it is noted that because the combination of Shirley and Dorin provide the motivation to create stabilized IFN-β compositions comprising acetate buffer, 2-hydroxypropyl-beta-cyclodextrin, manntiol, an anti-oxidant (EDTA), and a bacteriostatic agent, it is noted that a person of ordinary skill in the art would have the motivation, and the ability, to optimize the concentrations or amounts of various reagents in order to create the most effectively stabilized formulation. MPEP 2144.05 states:

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 454, 105 USPQ 223, 235, (CCPA 1955).

In the instant case, the combination of Shirley and Dorin teach the general conditions of the claims, namely that of a stabilized liquid composition comprising IFN, including recombinant IFN-b, and a buffer (acetate buffer), 2-hydroxypropyl-beta-cyclodextrin, an isotonicity agent (mannitol), an anti-oxidant (EDTA), and a bacteriostatic agent. Therefore, would not be inventive to optimize the concentrations or amounts of these agents and the limitations of claims 7, 10-11, 13-14, 16, and 21-22.

2. Claims 12, 20, 23-24, 32-35, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shirley *et al* ("Shirley" - US 2002/0172661) in view of Dorin *et al* ("Dorin" - US 5,814,485), and further in view of Chen *et al* ("Chen" – US 6,569,420).

The subject matter of the presently claimed invention is discussed above. Claims 12 and 23-24 are further drawn to the stabilized pharmaceutical composition of claim 1, wherein the antioxidant is methionine, while claim 20 recites the composition of claim 1 with the specific bacteriostatic agent benzyl alcohol. Claims 32-35 and 37 are drawn to an article of manufacture comprising stabilized liquid pharmaceutical composition comprising an IFN, including recombinant IFN-β, and a buffer such as acetate buffer, 2-hydroxypropyl-beta-cyclodextrin, an isotonicity agent such as mannitol, an anti-oxidant such as methionine, and a bacteriostatic agent such as benzyl alcohol, and a hermetically sealed container comprising said composition. Also claimed is an article of manufacture wherein said container is for mono-dose or multi-dose administration, including a pre-filled syringe for mono-dose administration, a vial, or a kit comprising said pharmaceutical composition and a bacteriostatic agent.

The disclosures of Shirley and Dorin are discussed above. Shirley further teaches stabilized liquid IFN-β formulations in sealed vials suitable for unit-dose or multi-dose (paragraph 0074), and specifically teaches liquid formulations in pre-filled syringes for single-dose or multi-dose administration (paragraph 0048). Neither Shirley nor Dorin specifically teach a stabilized composition comprising IFN-β comprising methionine and/or benzyl alcohol.

However, Chen teaches that IFN compositions can be formulated using both methionine and benzyl alcohol (column 39, line 65 - column 40, line 1). Therefore, a person of ordinary skill in the art would have been motivated to incorporate methionine and/or benzyl alcohol into the stabilized formulation comprising an IFN, including recombinant IFN-β, and a buffer such as acetate buffer, an

isotonicity agent such as manntiol, and hydroxypropyl-beta-cyclodextrin. The motivation to create a composition comprising IFN, acetate buffer, manntiol, hydroxypropyl-beta-cyclodextrin and EDTA is discussed above. Furthermore, because Chen teaches that methionine and benzyl alcohol are useful excipients for formulating IFN compositions, a person of ordinary skill in the art would be motivated to incorporate these agents into the composition. Although the combination of Shirley, Dorin, and Chen do not explicitly teach the amounts of each reagent cited in claim 24, as stated above, because Shirley, Dorin, and Chen teach the general conditions of the claim, it would be obvious to optimize the amount of each reagent.

Regarding the article of manufacture recited in claim 32, it is noted that the instant specification states that an article of manufacture can be a vial comprising the claimed pharmaceutical composition. Shirley teaches that stabilized liquid pharmaceutical compositions of IFN-β can be stored in sealed vials which are suitable for single-dose or multi-dose administration, and therefore a person of ordinary skill in the art would be motivated to create an article of manufacture, such as a vial comprising IFN-β and acetate buffer, mannitol, hydroxypropyl-beta-cyclodextrin, methionine, and/or benzyl alcohol, as suggested by the combination of Shirley, Dorin, and Chen, wherein this vial is suitable for single-dose or multi-dose administration. Furthermore, although neither Shirley, Dorin, nor Chen specifically teach kits comprising a stabilized pharmaceutical composition, it is noted that by teaching sealed vials formulated for single- or multi-dose administration, Shirley would provide the motivation to incorporate these articles of manufacture/vials into a kit, as such kits are well-known to a person of ordinary skill in the art.

3. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shirley *et al* ("Shirley" - US 2002/0172661) and Dorin *et al* ("Dorin" - US 5,814,485), in view of Chen *et al* ("Chen" – US 6,569,420), and further in view of Tsals *et al* ("Tsals" – US 5,858,001).

The subject matter of the presently claimed invention is discussed above. Claim 36 is further drawn to an article of manufacture comprising the claimed stabilized pharmaceutical composition in a container for mono-dose or multi-dose administration, wherein the container is a cartridge for an auto-injector.

The teachings of Shirley, Dorin, and Chen are discussed above. None teach a cartridge for an auto-injector. However, Tsals teaches a cartridge-based drug delivery device that is an auto-injector comprising a cartridge that serves as a reservoir (see abstact; claim 1). Tsals also teaches that this device is suitable for administration of IFN formulations, including IFN-α, -β, and -γ (column 7, lines 4-9).

Therefore, a person of ordinary skill in the art, at the time the present invention was conceived, would have been motivated to incorporate a liquid pharmaceutical composition comprising IFN, including recombinant IFN-β, and a buffer such as acetate buffer, an isotonicity agent such as manntiol, hydroxypropyl-beta-cyclodextrin, methionine, and/or benzyl alcohol, as is obvious in view of Shirley, Dorin, and Chen, into the drug delivery device of Tsals because Shirley teaches IFN-β formulations in a container for mono- or multi-dose administration, and Tsals teaches a specific device for drug administration which contains a container/reservoir for storing liquid pharmaceuticals.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-25 and 32-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of commonly owned and copending Application No. 10/554,602, in view of Dorin *et al.* Although the conflicting claims are not identical, they are not patentably distinct from each other.

The '602 application is drawn to stabilized human serum albumin (HSA)-free liquid pharmaceutical compositions of IFN, including recombinant IFN-β, comprising a buffer such as acetate buffer, an isotonicity agent such as manntiol, an anti-oxidant such as methionine, and/or a bacteriostatic agent such as benzyl alcohol. Also claimed are sealed containers comprising this formulation, wherein said containers are suitable for mono-dose or multi-dose administration, or are vials or pre-filled syringes.

Therefore, both applications are drawn to stabilized liquid pharmaceutical compositions comprising IFN-β and acetate buffer, manntiol, methionine, and/or benzyl alcohol, and the present application also states that the formulations are preferably HSA-free (p. 5, lines 4-8). Although the '602 application does not recite IFN formulations comprising 2-hydroxypropyl-beta-cyclodextrin, as discussed above, Dorin teaches that this is a useful additive for IFN formulation, and thus it would be obvious to a person of ordinary skill in the art to incorporate 2-hydroxypropyl-beta-cyclodextrin into the formulation of the '602 application. For these reasons, a person of ordinary skill in the art would readily conclude that the subject matter of the '602 application is an obvious variant of the present application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 1-25 and 32-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 32-45, 48-57, and 60-61 of commonly owned and copending Application No. 11/597,987, in view of Dorin *et al.* Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claims of the '987 application are drawn to a stabilized HSA-free pharmaceutical composition of IFN comprising a buffer, an amino acid, and an antioxidant. The claims are further drawn to the pharmaceutical composition wherein the IFN is recombinant IFN-b, and wherein a buffer is present in an amount sufficient to maintain the pH of the composition within plus or minus 0.5 units of a specified pH, wherein the specified pH is about 3.5 to about 5.5. Also claimed in the '987 application is acetate buffer as the preferred buffer, lysine as the preferred amino acid, methionine as the preferred antioxidant, and various surfactants and bacteriostatic agents, including benzyl alcohol. Although the '987 application does not recite IFN formulations comprising 2-hydroxypropyl-beta-cyclodextrin, as discussed above, Dorin teaches that this is a useful additive for IFN formulation, and thus it would be obvious to a person of ordinary skill in the art to incorporate 2-hydroxypropyl-beta-cyclodextrin into the formulation of the '987 application. Furthermore, although the present application does not specifically claim IFN compositions comprising surfactants or the amino acid lysine, it is noted that the instant specification teaches that both surfactants (p. 3, line 22) and lysine (p. 10, line 27) can be included in pharmaceutical compositions comprising IFN. For these reasons, a person of ordinary skill in the art would readily conclude that the subject matter of the '987 application is an obvious variant of the present application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571)272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bruce D. Hissong
Art Unit 1646

/Robert Landsman/
Primary Examiner, Art Unit 1647